

NOV 13 2003

2320 NW 66TH COURT  
GAINESVILLE, FL 32653

352-377-1140  
FAX 352-378-2617

K032964

**Exactech®**  
**Alumina Femoral Heads**  
**12/14 M-Series Neck Segments**

**510(k) Summary of Safety and Effectiveness**  
**Special 510(k)**

**Sponsor:** Exactech® Inc.  
2320 N.W. 66<sup>th</sup> Court  
Gainesville, Florida 32653

**Phone:** (352) - 377 - 1140  
**Fax:** (352) - 378 - 2617

**FDA Establishment Number 1038671**

**Contact:** Gary J. Miller  
Exec. V.P. of Research & Development

**Date:** October 22, 2003

rev. 10/22/03

Section 4  
Page 1 of 4

**Exactech®**  
**Alumina Femoral Heads**  
**12/14 M-Series Neck Segments**

**510(k) Summary of Safety and Effectiveness**  
**Special 510(k)**

Trade / Proprietary Name: Exactech

Model Name: 12/14 Alumina Femoral Head

Classification Name: Prosthesis, Hip, Semi-Constrained,  
Metal/Ceramic/Polymer, Cemented  
or Non-Porous, Uncemented

Product Code: LZO

C.F.R. Section: not specified

Device Class: II

Classification Panel: Orthopedic

---

Trade / Proprietary Name: Exactech AcuMatch

Model Name: M-Series 12/14 Neck Segment

Name: Prosthesis, Hip, Semi-Constrained, Metal/Polymer,  
Porous, Uncemented

Product Code: LPH

C.F.R. Section: 888.3358

**Legally Marketed Devices for Substantial Equivalence Comparison:**

Exactech Zirconia Ceramic Femoral Head	#K914574
	#K931617
Exactech AcuMatch M-Series Femoral Stems (Neck Segments)	#K010120

**Exactech®**  
**Alumina Femoral Heads**  
**12/14 M-Series Neck Segments**

**510(k) Summary of Safety and Effectiveness**  
**Special 510(k)**

**Device Description:**

**INDICATIONS**

All Exactech Hip Systems are indicated for use in skeletally mature individuals undergoing primary surgery for hip replacement due to osteoarthritis, rheumatoid arthritis, osteonecrosis, post-traumatic degenerative problems of the hip, and for treatment of proximal femoral fractures where prosthetic replacement is determined by the surgeon as the preferred treatment. Components of Exactech Hip Systems are also potentially indicated for ankylosing spondylitis, congenital hip dysplasia, revision of failed previous reconstructions where sufficient bone stock is present, and to restore mobility resulting from previous fusion.

AcuMatch M-Series 12/14 Neck Segments and Exactech 12/14 Alumina Femoral Heads are intended to be used in press-fit and cemented applications.

**CONTRAINDICATIONS**

Exactech Hip Systems are contraindicated in patients with active infection, patients without sufficient bone stock to allow appropriate insertion and fixation of the prosthesis, in neuromuscular disorders that do not allow control of the hip joint, and in patients whose weight, age, or activity level would cause the surgeon to expect early failure of the system. The L-Series unipolar and bipolar endoprotheses are also contraindicated for use in patients with evidence of degenerative changes in the acetabulum and/or pelvic fractures.

**Exactech 12/14 Alumina Femoral Heads**

This Special 510(k) application supports design changes to the proposed BIOLOX<sup>®</sup>forte 12/14 Ceramic Femoral Heads relative to Exactech's predicate Zirconia Ceramic Femoral Heads (#K914574, #K931617). The modifications include a change in the ceramic material composition from zirconia to alumina and a change in the taper geometry from a proprietary 11/13 design to a European 12/14 design.

The proposed Ceramic Femoral Heads are composed of CeramTec BIOLOX<sup>®</sup>forte alumina material and have a European 12/14 bore design. The material properties of BIOLOX<sup>®</sup>forte are described in FDA Master Files MAF-197, MAF-746, and MAF-747.

**Exactech®**  
**Alumina Femoral Heads**  
**12/14 M-Series Neck Segments**

**510(k) Summary of Safety and Effectiveness**  
**Special 510(k)**

**AcuMatch M-Series 12/14 Neck Segments**

This Special 510(k) application supports modification of the AcuMatch M-Series neck segments (#K993736, #K010120). Modifications were made to the femoral stem cone design, neck geometry and through-hole diameter. The material composition, surface finish, neck angle, neck length and metaphyseal taper connection are unchanged.

**Conclusion:**

Testing and engineering evaluations were conducted to verify that the performance of the new 12/14 alumina heads and the 12/14 neck segments would be adequate for anticipated *in vivo* loading. Based on successful results we conclude that the proposed devices are substantially equivalent Exactech's predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

NOV 13 2003

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Lisa Simpson  
Senior Regulatory Representative  
Exactech, Inc.  
2320 NW 66<sup>th</sup> Court  
Gainesville, Florida 32653

Re: K032964

Trade/Device Name: Exactech 12/14 Alumina Femoral Head,  
Exactech AcuMatch M-Series 12/14 Neck Segment

Regulation Number: 21 CFR 888.3358, 21 CFR 888.3353

Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated  
uncemented prosthesis, Hip joint metal/ceramic/polymer semi-  
constrained cemented or nonporous uncemented prosthesis

Regulatory Class: II

Product Code: LPH, LZO

Dated: October 22, 2003

Received: October 23, 2003

Dear Ms. Simpson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

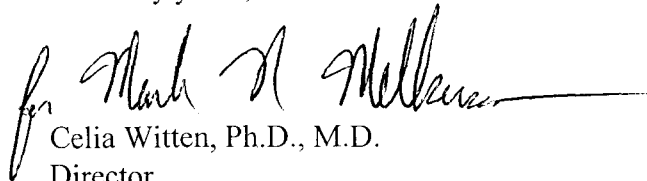
Page 2 - Ms. Lisa Simpson

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "for Mark A. Miller", is written over the typed name "Celia Witten, Ph.D., M.D.".

Celia Witten, Ph.D., M.D.

Director

Division of General, Restorative  
and Neurological Devices

Office of Device Evaluation

Center for Devices and  
Radiological Health

Enclosure

**Exactech 12/14 Alumina Femoral Head  
Exactech AcuMatch M-Series 12/14 Neck Segment**

**Indications for Use**

510(k) Number: K032964

**INDICATIONS**

All Exactech Hip Systems are indicated for use in skeletally mature individuals undergoing primary surgery for hip replacement due to osteoarthritis, rheumatoid arthritis, osteonecrosis, post-traumatic degenerative problems of the hip, and for treatment of proximal femoral fractures where prosthetic replacement is determined by the surgeon as the preferred treatment. Components of Exactech Hip Systems are also potentially indicated for ankylosing spondylitis, congenital hip dysplasia, revision of failed previous reconstructions where sufficient bone stock is present, and to restore mobility resulting from previous fusion.

AcuMatch M-Series 12/14 Neck Segments and Exactech 12/14 Alumina Femoral Heads are intended to be used in press-fit and cemented applications.

**CONTRAINDICATIONS**

Exactech Hip Systems are contraindicated in patients with active infection, patients without sufficient bone stock to allow appropriate insertion and fixation of the prosthesis, in neuromuscular disorders that do not allow control of the hip joint, and in patients whose weight, age, or activity level would cause the surgeon to expect early failure of the system.

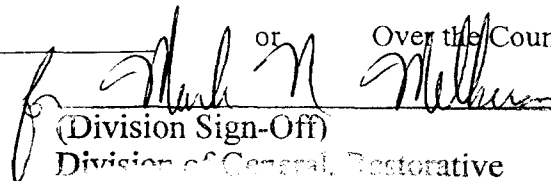
Please do not write below this line - use another page if needed.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use

or

Over the Counter Use

  
(Division Sign-Off)  
Division of General, Restorative  
and Neurological Devices

rev. 10/22/03

510(k) Number K 032964

Section 3  
Page 1 of 1